REMARKS

Claims 1-7, 10-22, 33, 34, 45 and 47-62 are pending in the application. Claims 23-32, 35-44 and 46 had been cancelled pursuant to an earlier restriction requirement. Claims 8 and 9 were cancelled in the prior Response. Pursuant to the Office Action dated July 29, 2005, all claims stand rejected. By this response, Applicants respectfully request reconsideration of the rejections in light of the following comments.

Claim Rejections

Rejection under 35 USC §103(a) over Trogolo et. al. (US 6,436,422) in view of Michal et. al. (US 6,287,285) and Schink et. al. (US 2001/0009831)

The Patent Office has rejected claims 1-7, 10-22, 33, 34, 45 and 47-62 under 35 USC §103(a) as being unpatentable over Trogolo et. al. in view of Michael et. al. and Schink et. al. In forming its rejection, the Patent Office characterizes the present invention as being directed to a high aspect ratio microcapsule comprising an antimicrobial agent coated with a hydrophilic polymer, said microcapsule having an aspect ratio of greater than about 2 and being in various shapes including flakes, fibers, etc. Trogolo et. al. is cited as disclosing an antibiotic coated substrate having an antibiotic coating composition formed of a hydrophilic polymer, including polyurethane, having antibiotic ceramic particles, preferably antibiotic zeolite, dispersed therein, alone or in combination with a discoloration inhibiting agent. The so formed antibiotic coating compositions, which may comprise 0.01 to 90% of the antibiotic zeolite and 10 to 99.99% hydrophilic polymer, may be employed in a number of applications and applied to a variety of substrates. It is stated that Trogolo et. al. is lacking in that it fails to recite microcapsules and is also silent as to the aspect ratio, specifically an aspect ratio of greater than about 2. Schink is cited as disclosing antimicrobial wound dressings comprising a synthetic polymer, including polyurethane, containing zeolites and metal ions. The Patent Office alludes to Paragraphs 0066 and 0067 of Shink et. al. as disclosing "that their invention is made of particles." Although Michael et. al. is cited in the statement of the rejection, no other reference to or discussion of Michal et. al. is set forth in the rejection.

In presenting its rejection the Patent Office states: "While the reference is silent regarding the aspect ratio, difference in the aspect ratio will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such an aspect ratio is critical. Where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Trogolo discloses the similar coated particles as desired by Applications. Trogolo discloses sheets, sbers [sic] and cylinders (figure 1 and col. 5). Therefore, absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the shapes invented by Trogolo and apply it inside a particle motivated by the teaching of Schink to determine a suitable aspect ratio to achieve the desire results."

Applicants respectfully traverse the rejection and request reconsideration. Although the rejection is somewhat awkward in its presentation, Applicants believe they understand it sufficiently to respond.

First, the Patent Office has misconstrued/misapplied the cited references. Trogolo et. al. teach liquid hydrophilic coating compositions which, when applied to various substrates and the solvent is allowed to evaporate, leaves an antimicrobial hydrophilic polymer film or coating on the substrate surface. Trogolo et. al. teach that the coatings may be applied to any number of substrates, essentially all of which are articles of manufacture or stock materials, including medical devices such as stents, building materials such as house wrap, woven and non-woven fabrics and the like. Even reading Trogolo et. al. in a light most favorable to the Patent Office, i.e., that Figure 1 shows a cylinder and/or fiber (actually it's a portion of a catheter) or that Col. 5's reference to fabrics suggests sheets, nothing would suggest that the coating compositions could have any utility beyond that of a coating or film forming material.

It appears, though it is not clear, that the Patent Office presumes that Schink et. al., specifically paragraphs 0065 – 0067, would motivate or suggest the formation of particles of the composition of Trogolo et. al. While Schink et. al. do reference particles, it is clear that they are referring to particles of the antimicrobial active agent itself, i.e., the zeolites, the very same antimicrobial agents that are employed in Trogolo et. al. as well as are suitable for use in the practice of the present invention. Perhaps the Patent Office is unaware; however, antimicrobial zeolites and like antimicrobial agents are naturally and inherently in particle form. Thus, when each refers to use of particles of the antimicrobial agent, it is referring to the neat antimicrobial agent. However, nothing in either Trogolo et. al. or Schink et. al. nor in their combined teachings suggests, infers or motivates one to form antimicrobial additive particles comprising a plurality of particles of the antimicrobial active agent dispersed in a hydrophilic polymer let alone wherein such additive particles having an aspect ration of greater than 2.

Furthermore, although both Trogolo et. al. and Schink et. al. employ polyurethanes, the polyurethane is a matrix material in which the particles of the neat antimicrobial active agent are incorporated. In Trogolo et. al., the composition is in liquid form, in solution, for application to a substrate where, following application, it forms a continuous film or coating on the surface of the substrate. In Schink et. el. the composition is in the form an antimicrobial wound dressing. As noted above, neither reference teaches or suggests forming micron sized particles of the therein disclosed antimicrobial polymer compositions. In following, nothing suggests, infers or motivates one to prepare micron sized particles of a hydrophilic polymer having dispersed therein particles of an inorganic antimicrobial agent for use as an additive to polymer compositions, including coatings and the like, for the purpose of providing improved antimicrobial efficacy as compared to the incorporation of neat antimicrobial additives in such polymer compositions.

The second ground of the Patent Office's rejection, i.e., that the aspect ratio is a matter of optimization or finding a workable range, is also without merit. Essentially, this rejection is moot in light of the failure of the Patent Office to even establish the antimicrobial additive particles themselves as unpatentable. Nevertheless, the aspect ratio is not a matter of optimization or routine experimentation. Although this invention is an extension of and dominated by the invention disclosed and claimed in the copending, companion application of Applicants, USSN 10/032,372, it represents a unique and beneficial subset thereof. Specifically, as discussed in the present specification, the use of such high aspect ratio antimicrobial additives markedly increases the antimicrobial efficacy and/or the antimicrobial longevity of the polymer compositions, particularly non-hydrophilic polymer compositions, into which they are incorporated. As discussed in the attached Technical Memo entitled "Technical Comparison of

AgION Antimicrobial to Nanoparticulate Silver" (AgION TM-9) by Jeffrey A, Trogolo PhD, a co-inventor on the present application, the particle size of an inorganic antimicrobial agent greatly influences the performance of that antimicrobial agent. Specifically, in polymer compositions having the same loading of antimicrobial agent, Dr. Trogolo found that the use of larger particle sizes, even with lower (in that case one-fourth the amount) silver contents, results in higher overall silver release and, thus, improved performance, especially longevity performance. By analogy, the use of high aspect ratio antimicrobial additive particles can only increase the likelihood that a surface of the particle will come in contact with or close proximity to the surface of the polymer matrix into which it is incorporated; thereby being active in providing antimicrobial activity. As noted in the specification and as known to those skilled in the art, only those antimicrobial agents at or, perhaps, in close proximity (on a molecular scale) to the surface of the hydrophobic polymer in which they are incorporated are available to participate in providing antimicrobial activity. Antimicrobial agent within the bulk of the hydrophobic polymer is not available unless or until there in a mechanism transport the antimicrobial active to the surface.

Furthermore, the high aspect ratio particles in accordance with the practice of the present invention will have less detrimental impact on the physical properties of the polymer composition into which they are incorporated than antimicrobial particles having a low aspect ratio but a diameter of the same or similar length as the largest dimension of the particles of the present invention. Similarly, the antimicrobial additive particles of the present invention will also provide a much larger reservoir of the antimicrobial active as compared to a low aspect ratio particle whose diameter is the same as or similar in length to the smallest dimension of the particles of the present invention. Thus, the aspect ratio does provide a marked and unexpected benefit that is not suggested by the art.

In view of the foregoing discussion, it is clear that the Patent Office has failed to substantiate prima facie obviousness of claims 1-7, 10, 22, 33, 34, 45 and 47-62 of the present application and, therefore, the rejection should be withdrawn and the claims passed on to allowance.

Rejection under 35 USC §103(a) over Trogolo et. al. (US 6,436,422) in view of Michal et. al. (US 6,287,285)

The Patent Office has rejected claims 1-22, 33, 34, and 45-62 under 35 USC §103(a) as being unpatentable over Trogolo et. al. in view of Michal et. al. Trogolo et. al. is cited for the reasons set forth above. In this instance, however, the Patent Office states that the deficiency in Trogolo et. al. is its failure to "disclose the microcapsule comprise a dopant, specifically sodium nitrate." Michal et. al. is cited as showing the use of nitric-oxide donor drugs, including sodium nitrate, as vasodilators for relaxing smooth muscles of a vessel in association with the use and implantation of hydrophilic polymer coated medical devices. It is asserted that both Trogolo et. al. and Michal et. al. teach medical devices, specifically stents, with a hydrophilic coating. The Patent Office thereby asserts that, "Absent unexpected results, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Trogolo et. al by adding a dopant specifically sodium nitrate as taught by Michal because the expectation of relaxing smooth muscles of a vessel prior to, during, and/or after angioplasty or stent

placement." In concluding, the Patent Office states that "The expected result would be a microcapsule comprising a hydrophilic polymer and antimicrobial agent and a dopant."

Applicants respectfully traverse the rejection and request reconsideration. The Patent Office's rejection on the basis that it would have been obvious to incorporate the nitric-oxide donor of Michal et. al. into the antimicrobial hydrophilic coatings of Trogolo et. al. for the benefits taught by Michal et. al. is irrelevant to the present invention. As noted above, there is no motivation, suggestion or inference in Trogolo et. al. for the preparation of micron-sized particles of a hydrophilic polymer having dispersed therein a plurality of particles of an antimicrobial active agent. Indeed, both Trogolo et. al. and Michal et. al. are concerned with modifications/enhancements to hydrophilic coatings: in the former the addition of an antimicrobial agent and in the latter the addition of a therapeutic agent, especially a nitric-oxide donor drug. Inasmuch as Trogolo et. al. do not in any way make obvious the high aspect ratio antimicrobial additive particles of the present invention, the rejection of the Patent Office fails before one even considers the disclosure of Michal et. al. If there is nothing to suggest the formation of the particles, then certainly there is nothing to suggest the further incorporation of a dopant into such particles.

Furthermore, for the sake of argument, even if the Patent Office were to identify additional art pertinent to the formation of the high aspect ratio antimicrobial particle additives of the present invention, further reliance upon Michal et. al. would not make obvious the use of a dopant in said particles. In one of the many teachings of Michal et. al., they disclose the use of certain nitric-oxide donor drugs in a hydrophilic polymer coating whereby, when used on an implant and the implant placed into the body of a patient, the nitric-oxide donor drug is released by the hydrophilic coating so as to interact with and cause the relaxation of cells of the smooth muscle tissue (see e.g., Col. 4, lines 54-65 and Col. 12, lines 30-36). In contrast the cation of the dopants employed in the practice of the present invention, e.g., the sodium ion of in the case of sodium nitrate, is consumed in an ion-exchange process whereby the sodium ion is taken up by and bound by the ion-exchange carrier concurrent with the release of the bound silver ions. Clearly, one would not look to Michal et. al. for a dopant for causing a quick release of the antimicrobial metal ions from an ion-exchange antimicrobial agent encased in a hydrophilic polymer since Michal et. al. need to release or otherwise expose the nitric-oxide donors to the smooth muscle tissue to be effective. If anything, those skilled in the art, looking at Michal et. al., would have avoided the use of nitric oxide donors in combination with antimicrobial agents, especially the ion-exchange type antimicrobial agents, for fear of losing or significantly compromising their therapeutic effect.

As previously noted, nothing in either reference, alone or together, makes in any way obvious or in any way suggests or infers or motivates one to prepare micron-sized particles comprising a hydrophilic polymer containing a plurality of particles of an antimicrobial agent in combination with a dopant. Similarly, nothing suggests or in any way would contemplate that such a combination would provide a synergistic property relative to the release of the antimicrobial agent and, hence, the antimicrobial efficacy of a hydrophilic coating incorporating both. Thus, it is clear that the rejection based on Trogolo et. al. in view of Michal et. al. is without merit and/or has been fully rebutted. Applicants respectfully request that the rejection be withdrawn and the application passed on to allowance.

Conclusion

In light of the foregoing discussion it is believe that the rejections under 35 USC 103(a) have been fully addressed and rebutted. Consequently, Applicants believe the claims, as now presented, are in proper form for allowance. Early and favorable reconsideration is respectfully requested.

Petition For Extension of Time

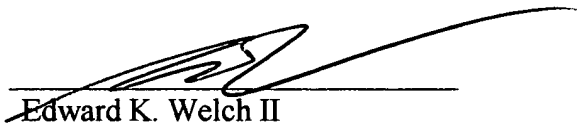
By this response, Applicants hereby petition for a one-month extension of time; thereby extending the response period from October 29, 2005 to and including November 29, 2005. Enclosed is a Credit Card Authorization in the amount of $60.00 as payment for the Petition Fee under 37 CFR 1.17(a)(1).

Claims Fees

No additional fees are owed as there have been no changes to the number of claims, independent or total.

Applicants believe all matters raised in the Office Action have been fully addressed. Should there be any questions, please contact the undersigned, Applicant's attorney.

Respectfully submitted,



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